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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,653	08/07/2003	Daopei Lu	077319-0373	8789

22428 7590 12/02/2005

FOLEY AND LARDNER LLP  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER
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PRYOR, ALTON NATHANIEL

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 12/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/635,653	<b>Applicant(s)</b> LU, DAOPEI	
	<b>Examiner</b> Alton N. Pryor	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 01 September 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1,5-10,60 and 61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1,5-8,60 and 61 is/are rejected.
- 7) ☐ Claim(s) 9 and 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 07 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

- A) Rejection of claims 11-13, 60 and 61 under 35 USC 112, 2<sup>nd</sup> paragraph will not be maintained. Applicant has amended claims 60 and 61 to be drawn to composition claims as oppose to method claims. Applicant has cancelled claims 11-13; therefore, rejection on record is moot.
- B) Rejection of claims 1,5 under 35 USC 102(b) as being anticipated by Yang will be maintained for reason on record and reason as follows. Claims 60 and 61 are added to this rejection.
- 1) Applicant argues:
- a) Instant invention excludes arsenic trioxide since claims employ consisting essentially of language and since claims 56-59, which add arsenic trioxide, have been cancelled.
  - b) Independent claim 1 has been amended to include therapeutic agents such as vincristine.
  - c) Dependent claim 60 is drawn to compositions having the utility to treat a number of cancer types.
  - d) Dependent claim 61 discloses that the composition is formulated as an oral formulation to be administered to a human.
- 1) Examiner argues:
- a) The use of "consisting essentially of" language does not necessarily exclude limitations (e.g. arsenic trioxide) which do not materially impact the invention. In this case, it appears that both the prior art

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and instant inventions are to the treatment of cancer; therefore, it appears that the presences of arsenic trioxide would not materially impact the invention (i.e. the invention with or without arsenic trioxide would still be effective at treating cancer and the presence of arsenic trioxide would not render the invention having some other utility.).

- b) Note that in claim 1 the therapeutic agent is optional; therefore, the therapeutic agent is not a required limitation.
- c) Yang teaches that his composition is used to treat cancer. However in a claim to a composition, a statement regarding intended use has no patentable significance.
- d) Yang teaches tablet dosage forms.

C) Rejection of claims 1,5, and 6 under 35 USC 102(e) as being anticipated by Ellison will be maintained for reason on record and reason as follows. Claims 60 and 61 are added to this rejection. Originally claims 7 and 8 were included in this rejection. However, upon further consideration claims 7,8 are added to new 103(a) rejections cited below. Note that Examiner is employing the USPN 6875451 instead of the USAN in previous office action.

- 1) Applicant argues:
  - a) "Ellison concluded that arsenic trioxide can be used to treat a broad range of cancers and, for this reason, Ellison's anticancer agent specifically comprises arsenic trioxide."

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- b) Instant invention excludes arsenic trioxide since claims employ consisting essentially of language and since claims 56-59, which add arsenic trioxide, have been cancelled.
  - c) Independent claim 1 has been amended to include therapeutic agents such as vincristine.
  - d) Dependent claim 60 is drawn to compositions having the utility to cancers such as leukemia.
  - e) Dependent claim 61 discloses that the composition is formulated as an oral formulation to be administered to human.
- 1) Examiner argues:
- a) Ellison teaches that a number of arsenic compounds including arsenic sulfides and arsenic trioxide being used to treat cancer. Ellison suggests that arsenic trioxide is the preferred cancer treatment agent. However, Ellison's anticancer agent does not specifically comprise arsenic trioxide. See column 8 line 48 – column 9 line 8.
  - b) The use of "consisting essentially of" language does not necessarily exclude limitations (e.g., arsenic trioxide) that do not materially impact the invention. In this case, it appears that both the prior art and instant inventions are to the treatment of cancer; therefore, it appears that presences of arsenic trioxide would not materially impact the invention (i.e. the invention with or without arsenic

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trioxide would still be effective at treating cancer and the presence of arsenic trioxide would not render the invention having some other utility.).

c) Ellison teaches that additional components such as vincristine can be added to his compositions. See column 6 line 36-57.

d) Ellison teaches that his composition is used to treat a number of cancer types including leukemia. See abstract, column 15 lines 15-43.

e) Ellison teaches that the composition can be formulated as an oral formulation for human delivery. See column 6 lines 8-35, column 9 lines 37-58.

D) Rejection of claims 58 and 59 under 35 USC 103(a) will not be maintained.

Claims 58 and 59 have been cancelled.

E) New 35 USC 103(a) Rejections

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang as applied to claims 1,5,60, and 61 above. Yang teaches all that is recited in claims 7 and 8 except for the composition comprising As<sub>4</sub>S<sub>4</sub> or 100 mg to 2 g of an

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arsenic sulfide. It would have been obvious to one having ordinary skill in the art to employ  $\text{As}_4\text{S}_4$ . One would have been motivated to do this since Yang teaches realgar which is an arsenic sulfide. Based on Yang's teaching, in the absence of unexpected results, one of ordinary skill in the art would expect other arsenic compounds such as  $\text{As}_4\text{S}_4$  to be effective in cancer treatment. With respect to 100 mg to 2 g arsenic sulfide, it would have been obvious to one having ordinary skill in the art to determine the optimum amount of arsenic sulfide to employ in the composition. One would have been motivated to do this in order to make a composition that would have been most effective and safe (reduced toxicity) in cancer treatment. It is very possible that the safe and effective amount of arsenic sulfide at the time of Yang's invention would have fallen within the range of arsenic (100 mg to 2 g) disclosed in the instant invention.

Claims 1,5-8,60,61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellison et al (USPN 6875451; 4/5/05). Ellison teaches a composition consisting essentially of one or more arsenic compounds (arsenous sulfide, arsenic sulfide, arsenic pentasulfide, tetrasulfide, arsenic trioxide) in a carrier (saline solution, water) to be used in cancer treatment (leukemia) of mammals / humans. Ellison teaches that arsenic trioxide is the preferred arsenic compound for treating cancer. See abstract, column 6 line 8- column 7 line 28. Ellison teaches that additional components such as vincristine can be added to his composition. See column 6 line 36-57.

Ellison teaches that the composition is administered orally at a daily dosage of about 10Ug to 200 mg. See column 12 line 47 – column 13 line 5. Applicant does not exemplify a composition comprising 100 mg to 2g arsenic sulfide, specifically  $\text{As}_4\text{S}_4$ . It

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would have been obvious to one having ordinary skill in the art at the time the invention was made to choose arsenic sulfide. One would have been motivated to do this since Ellison discloses a small group of cancer treating arsenic compounds (arsenic halides, arsenic oxides, arsenic acids, and arsenic sulfides), which includes arsenic sulfides.

See Ellison column 9 lines 1-8. One would have been motivated to try As<sub>4</sub>S<sub>4</sub> since Ellison teaches the use of arsenic sulfides broadly. See column 9 lines 1-8. With respect to 100 mg to 2 g arsenic sulfide, it would have been obvious to one having ordinary skill in the art to employ a composition comprising less than 200 mg of arsenic trisulfide (where instant and Ellison's invention overlap). One would have been motivated to do this because Ellison has suggests that this amount works and suggests that this amount is less toxic than greater amounts.

F) Objection to claims 9 and 10 on record will be maintained. The prior art does not teach or suggest the composition comprising plant semen.

#### ***Telephonic Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Alton Pryor', is written over the printed name.

Alton Pryor  
Primary Examiner  
AU 1616